REMARKS

Claims 21-36, 40-69, 76 and 77 are now pending in the above-referenced patent application. Applicants respectfully request further consideration of these claims, in view of the amendments set forth above and the following remarks.

Amended Claims

Claims 21 has been amended to correct a typographical error.

No new matter has been added.

Rejections Under 35 U.S.C. § 103(a) (Helmus, Tweden, Fearnot, Myers)

The Office action rejects all pending claims under 35 U.S.C. § 103(a) based on various combinations of references.

Applicants respectfully traverse these rejections in view of the current claim amendments.

Helmus, Tweden and Fearnot

Claims 21-30, 32-36, 41-69, 76 and 77 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., U.S. Patent 5,447,724 ("Helmus"), in view of Tweden et al., U.S. Patent 5,895,419 ("Tweden") and further in view of Fearnot et al., U.S. Patent 5,609,629 ("Fearnot").

Helmus discloses implantable medical devices having protective coatings applied to tissue exposed portions of the devices. The protective coatings include a release polymer that defines reservoirs for incorporating an agent in a manner that permits substantially free outward release of the agent from the reservoir to the tissue.

> The medical device has a tissue-exposed portion constructed to release an agent that inhibits adverse reaction to the presence of the device. The portion is defined by a polymer surface-layer overlying in a supported manner a polymer defining a reservoir. The reservoir incorporates the agent in a manner that permits substantially free outward release of the agent from the reservoir and the overlying layer defines metering outward passages constructed to control the outward migration of the agent to enable prolonged release of the agent from the surface of the medical device to prevent the adverse reaction due to the presence of the device.

Helmus, column 1, lines 37-49 (emphasis added).

The agent is released through an overlaying layer defining outward passages constructed to

control the outward migration of the agent from the surface of the medical device. Helmus also discloses that the articles may be constructed entirely from the release polymers. All of the embodiments of Helmus, whether describing the release polymer as a layer on the surface of the device or as a device material, all require the overlayer and elutable component for controlling release. *See* Helmus, column 9, lines 41-44 and 46-48.

Tweden discloses metallic coatings, such as silver on a prosthetic device to enhance acceptability of the implantable device. Tweden states in the first sentence of the Summary, "In contrast to the use of pharmaceutical products, the present invention includes an antimicrobial metallic coating on portions of the prosthesis, usually fabric, to enhance the overall acceptability of the implanted device." Tweden, column 1, line 65-column 2, line 1 (emphasis added). Thus, Tweden is limited to the use of metallic agents used with implantable medical devices.

Fearnot teaches the use of dexamethasone coated on medical devices.

The Office action suggests it would be obvious to combine the teachings of Helmus with those of Tweden and Fearnot to arrive at the claimed invention . Applicants respectfully traverse these rejections.

Applicants respectfully submit that one of skill in the art would not apply the teachings of Tweden to those of Helmus to incorporate a steroidal agent into a device as claimed, because Tweden explicitly states that its teachings are to use metallic coatings in contrast to pharmaceuticals. One of skill in the art looking to incorporate the teachings of Helmus would be led away from a reference that is directed to devices that are explicitly excluding the use of pharmaceuticals. For at least this reason, Applicants submit that the combination is improper.

Even if the combination is proper, Applicants respectfully submit that the combination does not result in the invention as claimed. The independent claims of the present invention require an annular support (claim 21), a body portion (claims 25, 41, 45, 52, 56 and 76), an annular insert (claims 60 and 76) or a polymer insert (claim 29) initially formed from a polymer mixed with a steroidal agent that provides at least one therapeutic effect to a polyester fabric overlayer. Helmus teaches eluting a therapeutic agent from a tissue contacting portion of a medical device, and Tweden teaches coating a fabric overlayer with a metallic coating. In contrast, a combination of Helmus and Tweden would result in using a metallic component such as silver utilized in a release polymer as taught in Helmus at the tissue contacting portion of the device, namely the fabric overlayer. Using the teachings of Helmus and the teaching of Tweden, one would coat or impregnate the fabric layer, not the support, body portion or polymer insert with the therapeutic agent to provide protection of this portion of the device.

Adding the specific teachings of Fearnont to use dexamethasone is inconsistent with the explicit teaching in Tweden that it is limited to metallic agents as opposed to pharmaceuticals. Furthermore, Fearnot does not address the other deficiencies in the combination, namely that the

support that is mixed with the steroidal agent provides a therapeutic effect to the fabric overlayer.

Furthermore, claims 76 and 77 recite (i) an annuloplasty ring consisting of a body portion overlaid by a polyester fabric overlayer, the body portion initially formed from a biostable polymer mixed with a releasable therapeutic agent wherein the releasable therapeutic agent provides a therapeutic effect to the fabric overlayer, and (ii) a method of making a medical sewing ring the method consisting: initially. forming the annular insert by mixing a releasable therapeutic agent with a biocompatible polymer; and enclosing the annular insert in a fabric sheath; wherein the releasable therapeutic agent provides at least one therapeutic effect to the fabric sheath.

Helmus requires the use of an overlayer with an elutable agent to control release of the active from the device. This requirement is in every embodiment of Helmus and is no teaching anywhere in Helmus that the release polymer can ever be utilized without the overlayer and elutable agent to control release of the therapeutic agent. Thus, claims 76 and 77 which are limited only to the recited elements, are patentable over Helmus.

Thus, for at least this reason, Applicants respectfully request the rejection be withdrawn.

Helmus, Tweden, Myers

Claim 31 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus in view of Tweden and Fearnot and further in view of Myers et al. U.S. Patent 5,716,397 ("Myers").

As discussed above, one of skill in the art would not be motivated to combine Helmus, Tweden and Fearnot as Tweden teaches away from the use of steroidals in implantable medical devices and the resulting devices would be designed to elute drug from the fabric overlayer, not the support. Adding the specific teachings of Myers to add a radiopaque salt does not cure the deficiencies in Helmus,Tweden and Fearnot.

For at least this reason, Applicants respectfully request the rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Examiner is hereby authorized to charge the fees required in connection with this Amendment to Deposit Account No. 13-2546, in accordance with the Transmittal submitted herewith. The Examiner is also authorized to debit any other fees required in connection with this application, or to credit any overpayment of fees in connection with this application to Deposit Account No. 13-2546.

Respectfully submitted,

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James H. Ackley
Reg. No. 45,695
Telephone: 763-505-2931
Facsimile: 763-505-2530
CUSTOMER NUMBER: 27581